

**Supporting Statement A**  
***Countermeasures Injury Compensation Program Information  
Collection***

**OMB Control No. 0915-0334**

**Terms of Clearance:** None

**A. Justification**

**1. Circumstances Making the Collection of Information Necessary**

This is a request for OMB approval of the updated information collection requirements for the Countermeasures Injury Compensation Program (“CICP” or “the Program”) Final Rule, which sets out the administrative policies, procedures, and requirements governing the Program (**Attachment A**) as authorized by the Public Readiness and Emergency Preparedness Act of 2005 (PREP Act). The Rule establishes procedures for the administrative implementation and data collection under the Program. The PREP Act (**Attachment B**), stipulates that (with limited exceptions) the CICP is to follow the Smallpox Emergency Personnel Protection Act of 2003 (SEPPA), the Smallpox Vaccine Injury Compensation Program (SVICP) regulations implementing SEPPA (**Attachment C**), and such additional or alternate regulations as the Secretary may promulgate. The required documentation from requesters filing for CICP benefits closely follows the SVICP requirements. The approved information collection requirements for the SVICP are approved under OMB No. 0915-0282. However, the SVICP no longer exists since the smallpox vaccine has been subsumed as a covered countermeasure under CICP.

On December 30, 2005, Congress enacted the PREP Act, which is part of the “Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006” (PL 109-148). The PREP Act confers broad liability protections on covered persons, as defined in section 319F-3(i)(2) of the Public Health Service (PHS) Act, and compensation to individuals injured by the administration or use of covered countermeasures, as defined in section 319F-3(i)(1) of the PHS Act, in the event of designated public health emergencies. Congress authorized the Secretary of the Department of Health and Human Services (Secretary) to issue regulations implementing the PREP Act.

The PREP Act provides the Secretary with the authority, which was delegated by the Secretary on November 8, 2006, to the Administrator of the Health Resources and Services Administration, to compensate eligible individuals for covered injuries from a covered countermeasure. The CICP is designed to provide compensation to individuals for serious

physical injuries or deaths from a pandemic, epidemic, or security countermeasures identified in declarations issued by the Secretary pursuant to section 319F-3(b) of the PHS Act.

The benefits available under the Program include compensation for reasonable and necessary medical care, lost employment income, and survivor death benefits, as explained in 42 CFR § 110.30-110.33. To be considered for Program benefits, requesters (*i.e.*, injured countermeasure recipients, survivors, the executors/administrators of the estates of deceased or injured countermeasure recipients), or persons filing on their behalf as their representatives, must file a Request for Benefits Form (Request Form) and submit the documentation required under the CICIP regulations to show eligibility.

Approval is requested for the following requirements and continued information collection activities as required by the CICIP Administrative Implementation regulations (42 CFR Part 110):

**42 CFR 110.10-110.11 Persons Eligible to Receive Benefits.**

This section lists the individuals who may be eligible to receive benefits from this Program.

**42 CFR 110.40-110.41 and 110.44-110.45 Filing a Request Package**

The Request for Benefits Package (Request Package) comprises the: Request Form, Authorization for Use or Disclosure of Health Information Form, medical records, Lost Employment Income Certification, Unreimbursed Medical Expenses Certification, and accompanying documentation to determine eligibility for benefits.

**42 CFR 110.42-110.43 Filing Deadlines**

All requesters (or their representatives) must file a complete Request for Benefits Package with the Secretary. All individuals requesting CICIP benefits, generally, must file a Request Package with the Secretary within one year of the date of the administration or use of a covered countermeasure that is alleged to have caused the injury or death. New requesters can obtain the Request Package and Instructions by calling 1-855-266-2427, sending an e-mail to [CICP@hrsa.gov](mailto:CICP@hrsa.gov), or downloading the materials from the internet at <https://www.hrsa.gov/cicp>. To be considered for benefits, the Form must be filed in accordance with § 110.42(c).

**42 CFR 110.46 Amendments to Request Packages.**

Section 42 CFR 110.46 provides the requirements for the filing of amendments to previously filed Request Packages.

**42 CFR 110.50-110.53 Documentation Needed for the Secretary to Determine Eligibility.**

Requesters (or their representatives) must submit appropriate documentation to allow the Secretary to determine if requesters are eligible for Program benefits. This documentation will vary somewhat depending on whether the requester is an injured countermeasure recipient, a survivor, or the executors/administrators of the estates of deceased or injured countermeasure recipients).

All requesters (or their representatives) must submit, or authorize their health care providers to submit, medical records sufficient to demonstrate that a covered injury was sustained by a covered countermeasure.

#### **42 CFR 110.60-110.63 Documentation Needed for the Secretary to Calculate Benefits.**

Requesters who are deemed eligible for benefits by the Secretary must submit documentation as specified in section 42 CFR 110.60-110.63 to allow the Secretary to determine the type(s) and amounts of benefits, if any, that will be paid to the requester. This documentation is in addition to the documentation submitted under §§ 110.50-110.53. This includes documentation needed to calculate benefits for reasonable and necessary medical services or items, benefits for lost employment income, and death benefits. This documentation will vary somewhat depending on whether the requester is an injured countermeasure recipient, a survivor, or an estate of a deceased, injured countermeasure recipient (through its executor/administrator). Since the Program's payment of benefits is secondary to all other third-party payers, the documentation requirements include information about any third-party payers that may have an obligation to pay for such benefits.

#### **42 CFR 110.90-110.92 Reconsideration of the Secretary's Eligibility and Benefits Determinations.**

Section 42 CFR 110.90-110.92 provides the requirements for requesters who seek reconsideration of the Secretary's eligibility or benefits determinations. No new documentation is considered in the reconsideration process.

## **2. Purpose and Use of Information Collection**

The CICP Administrative Implementation regulations (42 CFR Part 110) establish the procedures by which individuals may submit Requests for Benefits under the CICP. This collection of information provides data and documentation that will be used by the Secretary to determine that the Request for Benefits meets the requirements of the CICP. Each Request Package must include the required written documentation for the relevant individual described in §§ 110.10-110.11 in order for the Secretary to make a determination as to the requester's eligibility to receive benefits.

For each complete Request Package that is submitted, the Secretary shall determine whether the requester meets the requirements of eligibility. In order to make this determination, data must be

collected consisting of the filing of a Request Form and submission of medical records and other documentation required by §§ 110.50-110.53. The following requesters may be eligible to receive benefits:

- (1) Injured countermeasure recipients, as described in § 110.3(n).
- (2) Survivors, as described in §§ 110.3(cc) and 110.11.
- (3) Estates of deceased injured countermeasure recipients, as described in § 110.10(a)(3).

### **3. Use of Improved Information Technology and Burden Reduction**

Sections 110.40-110.46 describe how to obtain forms and instructions to apply for benefits, how to file a Request Package, and the deadline for submitting the Request Form and other documentation. Sections 110.50-110.53 identify the documentation required to determine eligibility. The CICIP can accept Request Packages and supporting documentation as hard copies or electronically through the CICIP website. Guidelines and instructions for collecting electronic records are also available on the CICIP website.

### **4. Efforts to Identify Duplication and Use of Similar Information**

The Request for Benefits package is unique to the CICIP and is not available elsewhere. Without this information, the Secretary would be unable to make a determination as to whether the Request for Benefits meets the requirements as specified.

The CICIP requests that medical records be submitted to the Program directly from the medical service providers to reduce and identify duplication and ensure authenticity.

### **5. Impact on Small Businesses or Other Small Entities**

No small businesses will be involved in this study.

### **6. Consequences of Collecting the Information Less Frequently**

Requesters are required to file only once for benefits; however, requesters also must provide updated information and records during the process, for purposes of determining eligibility and benefits. Without these data, the Secretary will not be able to determine whether individuals are eligible for benefits.

### **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

The request fully complies with the regulation.

## **8. Comments in Response to the Federal Register Notice/Outside Consultation**

### **Section 8A:**

A 60-day Federal Register Notice was published in the *Federal Register* on January 4, 2023, vol. 88, No. 2; pp. 358-360. There were no public comments. A 30-day Federal Register Notice was published in the *Federal Register* on March 24, 2023, vol. 88, No. 57; pp. 17860- 17861. HRSA received one public comment.

Comment: Respondent expressed concerns about how the CICIP program treats cases from disabled Americans. There was no comment regarding the information collection itself.

Response: HRSA forwarded the comment to the appropriate staff and responded to the commenter alerting them to this. Since this comment did not provide suggested changes to the information collection. No changes have been made to the information collection request.

### **Section 8B:**

The HHS Office of the General Counsel has reviewed all of the forms included in this package.

## **9. Explanation of any Payment/Gift to Respondents**

Respondents will not receive any payments or gifts.

## **10. Assurance of Confidentiality Provided to Respondents**

Access to these records is strictly limited to authorized users who are aware of their responsibilities under the Privacy Act and who are required to maintain Privacy Act safeguards with respect to such records. The CICIP System of Records Notice (09-15-0071) identifies authorized users.

## **11. Justification for Sensitive Questions**

The CICIP Request Package does not include any questions generally regarded as sensitive.

## **12. Estimates of Annualized Hour and Cost Burden**

### **12A. Estimated Annualized Burden Hours**

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours*
Request for Benefits Form and Supporting Documentation	100	1	100	11.000	1,100.00
Authorization for Use or Disclosure of Health Information Form	100	1	100	2.000	200.00
Additional Documentation and Certification	30	1	30	0.750	22.50
Benefits Package and Supporting Documentation	30	1	30	0.125	3.75
Total	260	--	260	--	1,326.25

\* In ROCIS, Additional Documentation and Certification form burden hours rounds up to 23; Benefits Package and Supporting Documentation rounds up to 4, and overall Total Burden Hours rounds up to 1,327.

**12B:**

This field is not applicable to this collection. The information for this collection will be done during respondent's personal time, so salary information is not relevant.

**13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs**

There is no capital or start-up cost associated with this data collection.

**14. Annualized Cost to Federal Government**

The estimated annualized cost to the Federal Government for this Program is approximately 15% FTE at a GS-9 level (\$64,957) for a total of \$9,744 and 30% FTE at a GS-15 level (\$155,700) for a total of \$46,710 for processing and reviewing each individual Request for Benefits.

**15. Explanation for Program Changes or Adjustments**

The burden has not changed from the burden shown in the current inventory.

**16. Plans for Tabulation, Publication, and Project Time Schedule**

HRSA is requesting a 3-year OMB clearance for this information collection. Statistical analyses of medical information or fact patterns of interest may be published in the medical literature without any personal identifiers.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The OMB number and Expiration date will be displayed on every page of every form/instrument.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.